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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MICROSPHERIX LLC, *Plaintiff*, v. MERCK SHARP & DOHME CORP., MERCK SHARP & DOHME B.V., AND ORGANON USA, INC., *Defendants.*	Civil Action No. 2:17-cv-03984-CCC-MF **JURY TRIAL DEMANDED** *Document Filed Electronically* [redacted]

PLAINTIFF'S OPENING CLAIM CONSTRUCTION BRIEF

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CHART 1: LIST OF CLAIM TERMS AND APPLICABLE PATENT CLAIM(S)[1]

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"hollow interior"	'401 Patent, Claims 1–5, 9, 10, 13–16, 18–21, and 23–25 '835 Patent, Claims 1, 3, 4, 10, 16, 17, and 20
"wherein the agent is disposed within the hollow interior of the tube"	'835 Patent, Claim 20
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[1] For the convenience of the Court, Chart 1 identifies terms proposed for construction and applicable patent claims.

I. INTRODUCTION

The patents-in-suit, U.S. Patent Nos. 8,821,835 (the "'835 Patent"), 9,636,401 (the "'401 Patent"), and 9,636,402 (the "'402 Patent") (collectively, the "Asserted Patents")[2] are generally directed to implantable devices that release a therapeutic agent and contain some form of marker material. (*See, e.g.*, '402 Patent at 3:66–4:5.)[3] After Merck's unsuccessful effort to invalidate the claims of the Asserted Patents via *inter partes* review (IPR) at the Patent Office, 27 claims remain in the case and the parties dispute 8 groups of terms (totaling 18 individual limitations[4]) from these claims.

Microspherix presents claim constructions that are firmly grounded in the intrinsic evidence and that reflect the plain and ordinary meaning of these terms. Merck's positions, on the other hand, stray from the intrinsic evidence via strained efforts to read limitations into the claims to manufacture non-infringement arguments. Merck's constructions ignore bedrock Federal Circuit claim construction law and are wholly unsupported by the intrinsic evidence. As discussed in detail below, Microspherix's proposed constructions are consistent with this bedrock law and should be adopted.

II. CASE BACKGROUND

Microspherix filed this action against Defendants on June 5, 2017. (D.I. 1; *see also* D.I. 27 (amended complaint).) Before answering, Merck filed IPR petitions challenging claims 1–19

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[2] The Asserted Patents are attached as Exhibit Nos. 1–3 to the Declaration of Tasha Gerasimow, filed concurrently herewith. All cited exhibits are attached to the Declaration of Tasha Francis Gerasimow, filed herewith.

[3] The Asserted Patents have substantially identical specifications, with differences in priority information of the respective patents. The '402 Patent is cited throughout for convenience, but comparable citations exist in the '835 and '401 Patents. Applicable patent claims for each term are identified in Chart 1, *supra*.

[4] The parties jointly propose only one term for construction; Merck has insisted the remaining 17 terms also require construction. (*See* Ex. 4 (7/28/2020 Defendant's Amended Proposed Terms for Construction); Ex. 5 (7/28/2020 Email Gerasimow to Blythe).)

of the '402 Patent, claims 1–5 and 9–25 of the '401 Patent, and claims 1–4, 9–12, and 14–20 of the '835 Patent on December 22, 2017, December 29, 2017, and February 9, 2018, respectively. IPR2018-00393 ("'402 IPR"); IPR2018-00402 ("'401 IPR"); IPR2018-00602 ("'835 IPR"). The Patent Trial and Appeal Board ("PTAB") instituted review of the '402 Patent and the '401 and '835 Patents (the "IPR Proceedings") on July 9, 2018 and July 23, 2018, respectively.[5] (D.I. 67.) This litigation was stayed pending IPR review.

During the IPR Proceedings the parties sought construction of a number of terms found in the Asserted Patents, including "strand," "marker component," "encapsulated," "radiopaque material" / "radio-opaque material," "seed," and "pore." (*See* '402 IPR, Paper 13, at 5–6; '402 IPR, Paper 43, at 6; '401 IPR, Paper 13, at 6; '835 IPR, Paper 13, at 7; '835 IPR, Paper 43, at 6.) Of the claim terms from the Asserted Patents currently in dispute, the PTAB construed "marker component" as "a component that is detectable by imaging technology" ('401 IPR, Paper 13, at 7; '835 IPR, Paper 13, at 10) and declined to construe "radiopaque material" / "radio-opaque material" as "not essential to resolving the dispute" ('402 IPR, Paper 43, at 7). The PTAB's constructions of these terms, to the extent they are relevant to the parties' current disputes, are discussed in more detail below.

After trial in the IPR Proceedings, the PTAB found that Merck had not demonstrated that any of the challenged claims of the '401 or '835 Patents, or that claims 6 and 9 of the '402 Patent, were unpatentable. ('401 IPR, Paper 44, § V, at 53; '835 IPR, Paper 43, § V, at 45; '402 IPR, Paper 43, § V, at 68.) The Federal Circuit affirmed. (No. 2019-2197, D.I. 45, at 2 (Fed. Cir. June

[5] Merck also filed an IPR against U.S. Patent No. 6,514,193 (the "'193 Patent"), but pursuant to Microspherix's request to conserve resources and streamline the proceedings, the challenged claims were canceled and adverse judgment entered as to the '193 Patent on April 15, 2019. The '193 Patent was subsequently dismissed from this action by party stipulation on July 20, 2020. (D.I. 88.)

9, 2020).) The stay in this case was lifted on August 10, 2020, and the parties resumed with the claim construction phase consistent with the schedule entered and amendments thereto. (D.I. 89.)

III. TECHNOLOGY BACKGROUND

Dr. Edward J. Kaplan is a practicing radiation oncologist who invented and patented novel implants for administering drugs to patients. Dr. Kaplan's inventions are disclosed and claimed in the Asserted Patents. Many of the terms in dispute are exemplified in Claim 1 of the '401 Patent, reproduced below, see underlining:

> 1. A flexible non-radioactive strand for implantation into a subject, comprising:
>
> a marker component configured to allow for the determination of the position of the strand within a target tissue, the marker component having a length extending along a centerline of the marker component between a first end and a second end and having a substantially continuous wall bounding a hollow interior;
>
> a biocompatible component; and
>
> a therapeutic, prophylactic, and/or diagnostic agent, wherein the marker, biocompatible component and agent are disposed within the hollow interior; wherein the length of the marker component is greater than the diameter of the hollow interior, and
>
> wherein the substantially continuous wall includes at least one opening adapted to allow the agent to pass out of the hollow interior wherein the strand do[es] not contain a radioisotope.

('401 Patent, Claim 1 (emphasis added).)

The independent claims of the Asserted Patents generally recite the following basic elements: (1) a flexible, non-radioactive "strand" (or in other claims, a "seed") for implantation, (2) a marker component, (3) a drug agent that is delivered to the patient, (4) a hollow interior wherein the agent is disposed, and (5) an "opening" (or in other claims, "cavities" or "pores") from which the drug agent can pass into the patient's body. The dependent claims recite additional

features such as shape, dimensions, configuration of marker component and agent, or specific markers, drug components, or release patterns.

The invention claimed in the Asserted Patents allowed doctors to deliver controlled-release drugs in new ways without invasive surgery, overcoming safety concerns in the prior art. In conventional brachytherapy pre-dating Dr. Kaplan's invention, doctors treated cancers at precise locations in a tumor. (*See* '402 Patent at 1:28–36.) Dr. Kaplan proposed a new therapy where "[a] drug or other therapeutically active substance or diagnostic can be included in the strand in addition to, or as an alternative to, a radioisotope." ('402 Patent at 3:67–4:3.) Among the features it may include in various possible embodiments, Dr. Kaplan's "strand" is: (1) implanted "without the need for invasive surgery"; (2) provides drug "deliver[y] in a controlled fashion over a relatively long period of time"; and (3) ensures safety by providing that "concentrations of the therapeutically active substance will be greater at the implantation site" and avoiding "deleterious effect . . . on healthy tissue located away from the implantation site." ('402 Patent at 4:12–14, 17–25.) Additionally, Dr. Kaplan's inventive open implants "contain a radiopaque material or other means for external imaging." ('402 Patent at 4:5–7.) The radiopaque marker allows the implants to be located with an X-ray, so that doctors can check the integrity and location of the implant without invasive surgery. ('402 Patent at 18:17–21.)

IV. PRINCIPLES OF CLAIM CONSTRUCTION

In *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), the Federal Circuit explained that claim construction involves determining the meaning of claim terms "to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." 415 F.3d at 1313. Determining the meaning of claim terms requires "read[ing] the words used in the patent documents with an understanding of their meaning in the field, and . . . knowledge of any special meaning and usage in the field." *Id.* Claim terms "must be understood

and interpreted by the court as they would be understood and interpreted by a person in that field of technology." *Id.*

The Court begins a claim construction analysis by examining the intrinsic evidence, which includes the claims, the specification, and the prosecution history. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). In reviewing intrinsic evidence, the Federal Circuit has "long emphasized the importance of the specification in claim construction." *Phillips*, 415 F.3d at 1315. It is "the single best guide to the meaning of a disputed term" and is usually "dispositive." *Id.* (citation omitted). The prosecution history can also be a useful tool in claim construction, as it can reflect the understanding of the patent applicant and the patent examiner as to the intended patent claim scope. *Id.* at 1317. The construction that stays true to the claim language and most naturally aligns with the patent's specification and prosecution history will be, in the end, correct. *Id.* at 1316. Consequently, "it is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited." *Liebel–Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004).

After consulting the intrinsic evidence, a court may then examine the extrinsic evidence, or "all evidence external to the patent and prosecution history." *Markman v. Westview Inst., Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995). However, extrinsic evidence is generally "less significant than the intrinsic record in determining the legally operative meaning of disputed claim language." *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004) (quotations omitted). Moreover, when relied upon, extrinsic evidence must be considered in view of the intrinsic evidence. *Phillips*, 415 F.3d at 1320 ("[E]xtrinsic evidence may be useful to the court, but it is

unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.").

V. PROPOSED CONSTRUCTIONS

A. "marker"; "marker component"

Claim Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"marker"	Plain and ordinary meaning, "material included for detection using standard imaging techniques"	"a substance less toxic than barium sulfate that is added to enhance imageability"
"marker component"	Plain and ordinary meaning, "component of a device that comprises a marker"	"the part of the seed/strand that is a marker"

The parties' dispute regarding the "marker" terms centers on whether a plain and ordinary meaning consistent with the intrinsic evidence should govern (Microspherix's position), or whether the Court should read in specific limitations regarding specific types of markers and their toxicities (Merck's position). Merck's bald effort to read in limitations to create a non-infringement argument runs afoul of the intrinsic evidence and Federal Circuit case law and must be rejected.

Microspherix's proposed constructions for both terms are straightforward, plain and ordinary meaning definitions drawn directly from the intrinsic evidence. Consistent with the plain and ordinary meaning, the specification explains markers are included in the claimed implants so that their location can be determined "using standard X-ray imaging techniques." (*See* '402 Patent at 18:17–25, 2:27–29.) The specification makes clear throughout that many types of "markers" can be used. For example, the specification states that "[r]adiopaque marker 30 can be made of ***any substance*** that can be detected by conventional X-Ray imaging techniques," followed by a

long list of possibilities. ('402 Patent at 10:25–11:10 (emphasis added).) The Background of the Invention further explains that "[m]arkers are ***typically*** made of high atomic number (i.e., "high Z") elements or alloys or mixtures containing such elements" ('402 Patent at 2:29–31 (emphasis added)), and then lists numerous examples of possible marker materials. ('402 Patent at 2:31–44.)

Merck does not seem to dispute the basic concept of what a marker is insofar as it agrees (via part of its proposed construction) that it is a component added to an implant to "enhance imageability." Where Merck strays, however, is in its effort to restrict the term "marker" to only substances that are ***less toxic*** than barium sulfate. As noted above, there is no support in anywhere in the patent for this incredibly narrow construction. Indeed, the patent never mentions toxicity when listing the various possible marker materials that might be used, let alone establishes any bright line as to what level of toxicity might be appropriate for use as a marker. Federal Circuit precedent is clear that when terms are used in their general sense, specific narrowing limitations should not be imported via their constructions. *See Phillips*, 415 F.3d at 1314 (rejecting construction that "baffles" should be limited to only "steel baffles"); *Automed Tech., Inc. v. Microfil, LLC*, 244 F. App'x 354, 357 (Fed. Cir. 2007) (rejecting narrowing construction because it would "fly in the face of the specification and would engraft onto the claims an unwarranted limitation").

Merck points to no evidence (because none exists) to contend that the plain and ordinary meaning of marker should include any reference to barium sulfate, let alone that a marker must be "a substance less toxic than barium sulfate." The Federal Circuit has made clear that it is appropriate to adopt the full scope of a term's plain and ordinary meaning, "***unless*** the patentee explicitly redefines the term or disavows its full scope." *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1367 (Fed. Cir. 2012) (emphasis added). A disavowal of claim scope applies to

claim construction only if the high burden of a "clear and unmistakable disclaimer" is met. *Id.* at 1367. There is nothing in the intrinsic evidence that comes close to meeting this high standard to deviate from the plain meaning.

While it is hard to imagine what Merck might try to point to in order to justify its strained construction of "marker," Microspherix expects Merck may rely on citations to the *inter partes* review proceedings and the Federal Circuit appeal that upheld the validity of the Asserted Patents. In those proceedings, Merck relied on obviousness combinations that included a prior art reference disclosing a barium sulfate marker material. Tellingly, however, neither the parties nor the PTAB or Federal Circuit ever contended that barium sulfate was ***not*** a marker, or that the toxicity of barium sulfate would exclude it from being considered a marker by a person of ordinary skill in the art ("POSA"). To the contrary, it was undisputed that barium sulfate was in fact a marker as a matter of plain meaning and as used in the Asserted Patents.[6] Merck's own expert from the IPR Proceedings confirmed Microspherix's plain meaning construction. (*See* Ex. 6 ('402 IPR, Ex. 1002, Langer Decl.) ¶139 (stating that at the time of the invention, "radiopaque markers had been used to make implants ***visible by common imaging techniques in the art***") (emphasis added).) And Merck's expert further confirmed that barium sulfate itself would in fact be considered a "marker" in the context of these patents. (*See* Ex. 7 ('402 IPR, Langer Dep. Tr.) at 63:2–13; 51:17–20 ("Q: What if the marker was a marker like barium sulfate? You're aware of barium sulfate as a use of a radiopaque marker, correct? A: Um-hum, yes.").)

[6] Merck's IPR arguments failed for reasons wholly unrelated to the construction of "marker" or "marker component", which was defined by the PTAB as "a component that is detectable by imaging technology." ('401 IPR, Paper 13, at 7; '835 IPR, Paper 13, at 10.)

The Court must reject Merck's brazen effort to read in a limitation that finds no support in the plain meaning of the term or any of the intrinsic evidence. Microspherix's plain meaning construction should be adopted.

B. "radiopaque" / "radio-opaque"; "radio-opaque material"; "agent . . . selected from the group consisting of . . . radiopaque"

Claim Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"radiopaque" and "radio-opaque"	"capable of visualization by conventional x-ray imaging"	"detectable by conventional x-ray imaging techniques"
"radio-opaque material"	"material that can be visualized by conventional x-ray imaging"	"a substance less toxic than barium sulfate[7] that can be detected by conventional x-ray imaging techniques"
"agent . . . selected from the group consisting of . . . radiopaque"	"agent … selected from the group consisting of … material that can be visualized by conventional x-ray imaging"	"a substance less toxic than barium sulfate that can be detected by conventional x-ray imaging techniques"

The parties' dispute regarding the "radiopaque" terms focuses on whether the material needs to be "detected" versus "visualized" using conventional X-ray techniques. Microspherix's position is that "radiopaque" requires the ability to ***visualize*** the device—in other words, to be able to form an image and identify what you are looking at. On the other hand, Merck's position suggests a device can be radiopaque as long as it is detectable at ***any*** level, regardless of whether the viewer can identify what he is looking at. Microspherix's position is more accurate and aligned with the intrinsic evidence and should be adopted.

[7] Insofar as Merck's proposed constructions for these terms also inject the "less toxic than barium sulfate" additional limitation, they are unsupported by the intrinsic evidence and Federal Circuit case law as discussed in detail above in § V.A.

The specification of the Asserted Patents supports Microspherix's construction of "radiopaque" and "radio-opaque material." The specification explains that the purpose of the marker is to help locate and determine the positioning of the implanted device: "[r]adiopaque marker 30 allows for the position of brachytherapy strand 10 to be determined using standard X-ray imaging techniques (e.g., fluoroscopy) after strand 10 has been implanted in a target tissue." ('402 Patent at 18:17–21.) The specification goes on to explain that a radiopaque marker is included with the device so that the "strand can be ***visualized*** by X-ray imaging." (*See* '402 Patent at 18:61–62 (emphasis added); *see also id.* at 19:3–13.) The specification makes clear a radiopaque marker is used to visualize the implanted device so that it can be tracked (and potentially retrieved) internally, consistent with Microspherix's construction. (*See* '402 Patent at 18:61–62.)

Even Merck's own expert has agreed with Microspherix's plain meaning construction. During the IPR Proceedings, Merck's expert admitted that "radiopaque markers had been used to make implants ***visible*** by common imaging techniques in the art." (Ex. 6 ('402 IPR, Ex. 1002, Langer Decl.) ¶ 139 (emphasis added).) He further explained how addition of radiopaque marker material to implants had "the benefit of making them x-ray ***visible*** to aid in their implantation and subsequent removal." (*See id.* at ¶ 32 (emphasis added).)

While Merck's construction is not significantly different than Microspherix's insofar as it requires only that the material can be "detected" as opposed to "visualized," the Court should reject Merck's construction as less aligned with the intrinsic evidence and because it injects unnecessary ambiguity. The ambiguity in Merck's proposed construction of "radiopaque" potentially opens the door to any prior art device that might show up with shadows, pixelated images, or cloudy images as being "radiopaque." This construction is inconsistent with the specification, which demonstrates that the strand should be capable of being visualized by X-ray imaging to be

radiopaque. (*See* '402 Patent at 19:3–13 ("entire strand can be ***visualized*** by X-ray imaging rather than only a portion of a strand") (emphasis added).) Accordingly, Microspherix's constructions, which are more consistent with the purpose of the patent and fully supported by intrinsic evidence, should be adopted.

C. "therapeutic agent"; "prophylactic agent"

Claim Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"therapeutic agent"	Plain and ordinary meaning, "agent that exerts a desired medically beneficial or physiological effect"	"an agent for the treatment of disease"
"prophylactic agent"	Plain and ordinary meaning, "agent for prevention of an undesired or non-beneficial physiological condition"	"an agent for the prevention of disease"

The parties' dispute on "therapeutic agent" and "prophylactic agent" focuses on whether a therapeutic and prophylactic agent must be only those agents that directly treat or prevent a particular ***disease***. Microspherix proposes plain and ordinary meanings that derive directly from the intrinsic evidence, which are "agent[s] that exerts a desired medically beneficial or physiological effect" and "agent[s] for prevention of an undesired or non-beneficial physiological condition." Merck asks the Court to narrow the terms to be limited to disease treatment and prevention despite broader disclosure throughout the intrinsic evidence.

Microspherix's proposed constructions are plain meaning usages that are directly supported by the specification. The specification on numerous occasions equates the concept of a "therapeutic" to something that exerts "a desired medically beneficial effect." ('402 Patent at 14:51–56 ("i.e. a therapeutically effective amount or an amount that exerts a desired medically beneficial effect"); *id.* at 16:36–41 ("the therapeutically active component 14 is a material that can

be [] implanted in a target tissue of an animal subject (e.g., a mammal such as a human patient) to exert an effect on the animal's physiology").) The specification further equates "prophylactic component" with this concept of a "therapeutically active component." (*See id.* at 14:21–35 (referring to "prophylactic component" as a "therapeutically active component").) The broad usage of these terms in the specification confirms they should not be construed narrowly to apply only to compounds used for direct treatment of ***disease***, where no such limiting language exists. *See Phillips*, 415 F.3d at 1324–28; *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 992 (Fed. Cir. 1999) ("[M]ere inferences drawn from the description of an embodiment of the invention cannot serve to limit claim terms.").

Consistent with Microspherix's construction (and in conflict with Merck's position), the specification lists numerous possible examples of "therapeutic" or "prophylactic" agents that go beyond drugs that directly treat or prevent a specific "disease" state. The specification states that "[a]ny of a wide range of therapeutic, diagnostic and prophylactic materials can be incorporated into the strands," including the following list of agents:

> The non-radioactive drug can take the form of stimulating and growth factors; gene vectors; viral vectors; anti-angio genesis agents; cytostatic, cytotoxic, and cytocidal agents: transforming agents; apoptosis-inducing agents; radiosensitizers; radioprotectants; hormones; enzymes; antibiotics; antiviral agents; mitogens; cytokines; anti-inflammatory agents; immunotoxins; antibodies; or antigens. For example, the non-radioactive therapeutic can be an anti-neoplastic agent such as paclitaxel, 5-fluorouracil, or cisplatin. It can also be a radiosensitizing agent Such as 5-fluorouracil, etanidazole, tirapazamine, bromodeoxyuridine (BUdR) and iododeoxyuridine (IUdR).

('402 Patent at 8:4–15.) Among those, the quintessential example evidencing that the claimed invention is not limited to disease treatment and prevention is hormones, which have a systematic effect, including, for example, preventing pregnancy. Indeed, Merck is on record admitting that hormones are therapeutic agents in the context of these patents. *See* '402 IPR, Paper 1, at 11 ("De

Nijs and Schopflin are directed to implants for delivering a therapeutic agent, a hormone, to produce a contraceptive effect.").

Merck's proposed construction is inconsistent with the specification because it would exclude certain therapeutic materials listed in the specification, such as hormones. And hormones in fact were also called out during prosecution as part of the claimed invention. (Ex. 8 ('402 Patent File History, Amendment (11/8/16)) at 4 ("New claim . . . specifies that . . . the therapeutic agent is a hormone.").) *See Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1369 (Fed. Cir. 2003) (finding district court's claim construction erroneously excluded an embodiment described in an example in the specification, where the prosecution history showed no such disavowal of claim scope); *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1305 (Fed. Cir. 2007) (rejecting proposed claim interpretation that would exclude disclosed examples in the specification); *Depomed, Inc. v. Sun Pharma Global FZE*, No. 11-3553 (JAP), 2012 WL 3201962, at *14–15 (D.N.J. Aug. 3, 2012) (rejecting construction that "reads out embodiments described in the specification and complicates a term that can be given its plain and ordinary meaning"). Accordingly, the Court should accord the terms their plain and ordinary meanings and reject Merck's litigation-driven constructions.

D. "target tissue"; "seed, for implantation into a subject"; "strand for implantation into a subject"; "strand for administration of a therapeutic agent to a subject in need thereof"

Claim Term[8]	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"target tissue"	Plain and ordinary meaning, "tissue into which implant is implanted"	"the tissue into which the implantation is intended and on which the agent acts to produce its intended effect"
"seed, for implantation into a subject"	Plain and ordinary meaning, "implant shaped to pass through a needle bore, for implantation into a subject"	"seed, for implantation into a subject at or near the site on which the agent acts to produced its intended effect"
"strand for implantation into a subject"	Plain and ordinary meaning, "elongated implant for implantation into a subject"	"strand for implantation into a subject at or near the site on which the agent acts to produced its intended effect"
"strand for administration of a therapeutic agent to a subject in need thereof"	Plain and ordinary meaning, "elongated implant for administration of a therapeutic agent to a subject in need thereof"	"strand for administration of a therapeutic agent that acts to produce its intended effect at or near the implantation site in a subject in need thereof"

The dispute regarding this collection of terms is whether the terms should be construed to strictly require, as proposed by Merck, that an implant must produce its intended therapeutic effect locally at the site of implantation. There is no support for this narrow construction, and the intrinsic evidence in fact refutes it. Proper construction of these terms reflects the simple notion that the target tissue is the intended (targeted) tissue for implantation.

[8] The terms "seed, for implantation into a subject," "strand for implantation into a subject," and "strand for administration of a therapeutic agent to a subject in need thereof" are grouped together with "target tissue" because they are all related to the parties' dispute regarding whether the extra limitation that the therapeutic effect takes place at the site of implantation is part of the term.

The asserted claims refute Merck's effort to read in limitations. First, Merck's position confuses the basic nature of the claims—the Asserted Claims are apparatus claims, not method of treatment claims. There are no method steps at all, let alone limitations how the therapeutic agents must be released and then interact with the body after delivery. The "target tissue" limitation comes up in the context of the strand containing "a marker component configured to allow for the determination of the position of the strand within the target tissue." (*See, e.g.*, '401 Patent, Claim 1) Nothing about this claim requires (1) actual placement of a strand in the target tissue, or (2) release of drug from the strand, or (3) that the strand remain in the target tissue for any length of time, or (4) that a therapeutic agent is released and acts on the tissue into which it is implanted. Merck effectively seeks to import ***all*** of these limitations into the claim, contrary to all of the intrinsic evidence and Federal Circuit law.

Beyond this fundamental misinterpretation and rewriting of the claims, Merck is wrong for additional reasons. While Merck tries to limit the claims to use of agents that would only have a local effect on the tissue adjacent to the implant, the claims of the patents contemplate delivery of therapeutic agents that would ***not*** merely act locally, but instead can provide some systemic benefit. For example, claim 15 of the '401 Patent specifies that the "agent" is selected from a group of numerous compounds that would typically be used for systemic effect as opposed to local treatment of the tissue immediately adjacent to the implant. ('401 Patent at 24:62–67). The specification of the '402 Patent lists hormones, antibiotics, antiviral agents, immunosuppressants, and stimulating and growth factors among other examples of therapeutic agents that are typically used for systemic rather than local effect. (*See* '402 Patent at 8:8–9:30.) Claims in a related family member underscore this, as claim 2 of the related '193 patent ***further limited*** "target tissue" to be "diseased tissue." This demonstrates that "target tissue" is clearly different and broader than

"diseased tissue," which arguably would be the site of intended (local) therapeutic effect. *See Trs. of Columbia Univ. in City of New York v. Symantec Corp.*, 811 F.3d 1359, 1370 (Fed. Cir. 2016) ("dependent claims [] are presumed to be narrower than the independent claims on which they depend").

Numerous references in the patent specification confirm that the invention broadly applies to therapeutic agents that can be released for systemic rather than strictly local effect. As discussed above, the specification teaches that therapeutic or prophylactic agents can be "implanted in a target tissue . . . to exert an effect on the ***animal's physiology***." ('402 Patent at 16:36–41 (emphasis added).) The specification contemplates that "diseased tissue" is just an ***example*** of the site of implantation, but is not (as Merck would require) the ***only*** type of "target tissue" that is contemplated. ('402 Patent at 4:21–23 (referencing "diseased tissue" as mere one example of an "implantation site").) And, as referenced in the prior section on "therapeutic agents," the patent clearly contemplates agents that produce systemic effects on broader parts of a subject's body rather than solely local effects on the immediately adjacent tissue. (*See* '402 Patent at 8:8–9:30.)

Not only does the patent include numerous potential examples of agents that would produce systemic rather than strictly local effects, the patent explicitly mentions when certain embodiments are contemplated for "local" effect. For example, after several columns listing "many different therapeutically active substances" that can be generally used in the context of the claimed invention, the specification states that "[t]he claimed brachytherapy seed or strand ***may also be used for local cancer therapy***." ('402 Patent at 10:1–2 (emphasis added).) It is thus clear from the patent that while there certainly "may" be embodiments in which the agent would be released for local effect, neither the invention nor the more general claim terms in the Asserted Patents are so limited. *See Phillips*, 415 F.3d at 1324–28; *Automed Tech.*, 244 F. App'x at 357.

The Court should thus adopt the Microspherix's plain and ordinary meaning constructions for the terms and reject Merck's litigation-driven proposals.

E. "polymeric coating"

Claim Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"polymeric coating"	Plain and ordinary meaning, "a layer of polymer"	"a layer of polymer that is formed as a result of applying it or building it up to cover the existing surface of the strand/implantable rod"

Claim 1 of the '402 Patent, from which asserted claims 6 and 9 depend, requires that the strand comprise "a polymeric coating" that "covers the strand." Microspherix proposes the Court give "polymeric coating" its plain and ordinary meaning as understood by a person of skill in the art at the time: "a layer of polymer." Merck proposes a narrowing construction that is inconsistent with the intrinsic evidence: "a layer of polymer that is formed as a result of applying it or building it up to cover the existing surface of the strand/implantable rod."

Merck's narrowing construction should be rejected because it impermissibly seeks to convert product claims 6 and 9 into product by process claims. Merck's proposal would require the polymeric coating to "be formed as a result of applying it or building it up to cover the existing surface of the strand/implantable rod." [redacted]

However, the intrinsic evidence does not support Merck's product by process construction. A product claim is not limited to the process by which it was made unless "the patentee has made clear that the process steps are an essential part of the claimed invention." *Cont'l Circuits LLC v.*

Intel Corp., 915 F.3d 788, 799 (Fed. Cir. 2019); *see also Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372–73 (Fed. Cir. 2000) ("A novel product that meets the criteria of patentability is not limited to the process by which it was made."). Nowhere does the '402 Patent or its file history make clear that the process of forming the polymeric coating, let alone by "applying it or building it up to cover the existing surface of the strand/implantable rod," is an essential part of the invention.

Instead, the specification demonstrates that the polymeric coating is not limited to being formed as a result of applying it or building it up to cover the existing surface of the strand/implantable rod. *See Vitronics*, 90 F.3d at 1582 (specification "is the single best guide to the meaning of a disputed term" and prosecution history "is often of critical significance in determining the meaning of the claims"). The '402 Patent's specification discloses multiple exemplary methods of using polymers "to form, or to coat, drug delivery devices such as strands or strands containing any of a wide range of therapeutic and diagnostic agents." ('402 Patent at 7:63–65.) For example, the specification discloses a "phase inversion method" of forming or coating seeds: "a polymer is dissolved in a good solvent" and "poured into a strong non-solvent for the polymer, to spontaneously produce . . . polymeric seeds, wherein the polymer is either coated on the particles or the particles are dispersed in the polymer." (*Id.* at 12:32–39 (emphasis added).) The '402 Patent also discloses that particles/seeds "can be formed and/or coated using fluidized bed techniques" such as "the Wurster air-suspension coating process for the coating of particles and seeds." (*Id.* at 13:36–14:19 (emphasis added).) Merck's proposed construction seeking to impose a specific method on claims 6 and 9 is inconsistent with this specification language and thus is improper. *See Jazz Pharm., Inc. v. Amneal Pharm., LLC*, No. 13-0391 (ES)(JAD), 2017 WL 5128748, at *13 (D.N.J. Nov. 6, 2017) (rejecting defendant's narrowing

construction as "inconsistent with the specification"); *see also Merck & Co. v. Teva Pharm. USA, Inc.*, 347 F.3d 1367, 1371 (Fed. Cir. 2003) ("[C]laims must be construed so as to be consistent with the specification, of which they are a part.").

Moreover, the same specification language cited above, disclosing multiple methods of using polymers to form or coat drug delivery devices, was cited during the prosecution of the '402 Patent as support for "polymeric coating" in a preliminary amendment prior to examination of the application that resulted in the '402 Patent. In the May 13, 2015 Preliminary Amendment, Microspherix amended the specification's priority history disclosure, cancelled claims 1–26, and proposed new claims 27–36. (*See* Ex. 10 ('402 Patent File History, Preliminary Amendment (5/13/15)) at 2–4.) Proposed claim 27, which is similar to eventually issued claim 1 of the '402 Patent, included the "polymeric coating" term. *Id.* at 3. As support for the term, Microspherix cited the specification language that "[p]oylmers can be used to form, or to coat, drug delivery devices such as strands or strands containing any of a wide range of therapeutic and diagnostic agents" ('402 Patent at 7:63–65) as disclosing that "polymers can be used to coat drug delivery devices such as strands." (*See* Ex. 10 ('402 Patent File History, Preliminary Amendment (5/13/15)) at 5.) Additionally, in the same Preliminary Amendment, Microspherix cited the portion regarding fluidized bed techniques ('402 Patent at 13:37–40) as disclosing "a method for coating particles, including seeds." (*See* Ex. 8 ('402 Patent File History, Preliminary Amendment (5/13/15)) at 5.) Thus, the prosecution history provides further support from the intrinsic evidence that "polymeric coating" should be given its ordinary and customary meaning of "a layer of polymer."

In sum, Merck's proposed construction improperly reads a process limitation into a product claim, is inconsistent with the intrinsic evidence, and thus should be rejected. *See Cont'l Circuits LLC v. Intel Corp.*, 915 F.3d 788, 799 (Fed. Cir. 2019) (refusing to "read a process limitation into

a product claim" where patentee did not make clear that process was "an essential part" of claimed electrical device and intrinsic evidence "merely indicate" a preference and include comparisons with prior art techniques) (citation omitted); *see also Vanguard Prods.*, 234 F.3d at 1372–73 (rejecting construction that would "convert product claim[] into claim[] limited to a particular process" where specification showed that "integral" was used to describe the product, not limit the claim to sole manufacturing process disclosed in the specification).

F. "hollow interior"; "wherein the agent is disposed within the hollow interior of the tube"; "[marker component] . . . having a substantially continuous wall bounding a hollow interior"; "[marker component] . . . having a substantially continuous wall along the length, the substantially continuous wall bounding a hollow interior"

Claim Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"hollow interior"	Plain and ordinary meaning, "interior space"	"an empty space defined by and inside the wall of the marker component"
"wherein the agent is disposed within the hollow interior of the tube"	Plain and ordinary meaning, "where in the agent is disposed within the interior space of the tube"	"wherein the agent is disposed within the empty space defined by and inside the wall of the marker component"
"[marker component] . . . having a substantially continuous wall bounding a hollow interior"	Plain and ordinary meaning, "[component of a device that comprises a marker] . . . having a substantially continuous wall bounding a hollow interior"	"The marker component itself constitutes a wall that defines the hollow interior."
"[marker component] . . . having a substantially continuous wall along the length, the substantially continuous wall bounding a hollow interior"	Plain and ordinary meaning, "[component of a device that comprises a marker] . . . having a substantially continuous wall along the length, the substantially continuous wall bounding a hollow interior"	"The marker component itself constitutes a wall that defines the hollow interior."

Certain claims of the '401 and '835 Patents require that the drug delivery device have a "hollow interior" or "wherein the agent is disposed within the hollow interior of the tube."[9] The dispute for these terms is whether they still require an "empty space" ***after*** the agent or other components are disposed within the strand or tube. Merck's proposal construes "hollow interior" in isolation and adds the further limitation of an empty space, inconsistent with both logic and the intrinsic evidence. Microspherix, on the other hand, interprets the term in the context of the entire claim language and the specification of the '401 and '835 Patents to simply require it be an interior space (that can be filled by other components).

As reflected in the claims of the '401 and '835 Patents, the term "hollow interior" does not exist in isolation, but rather requires something be disposed in it: "wherein the agent is ***disposed within the hollow interior*** of the tube." ('835 Patent, Claim 20 (emphasis assed).) Based on this contextual claim language, Microspherix correctly proposes that the terms be given their plain and ordinary meaning at the time, *i.e.*, "interior space" and "wherein the agent is disposed within the interior space of the tube."

Merck's approach of construing "hollow interior" in isolation ignores that "[p]roper claim construction . . . demands interpretation of the entire claim in context, not a single element in isolation." *See Hockerson-Halberstadt, Inc. v. Converse Inc.*, 183 F.3d 1369, 1374 (Fed. Cir. 1999); *see also Kyocera Wireless Corp. v. Int'l Trade Com'n*, 545 F.3d 1340, 1347 (Fed. Cir.

[9] The terms "[marker component] . . . having a substantially continuous wall bounding a hollow interior" and "[marker component] . . . having a substantially continuous wall along the length, the substantially continuous wall bounding a hollow interior" are included here because the dispute over the term boils down to a dispute over "marker component" and "hollow interior." "Marker component" was discussed above, *see supra* § V.A, and "hollow interior" is discussed here, therefore, the disputed aspects of these terms are addressed fully herein. Microspherix incorporates its arguments in support of the construction of the term marker component as applicable herein, and argues that its proposed construction for marker component is a straightforward plain meaning definition, drawn directly from the intrinsic evidence.

2008) ("[T]his court does not interpret claims terms in a vacuum, devoid of the context of the claim as a whole."); *Depomed, Inc. v. Banner Pharmacaps Inc.*, 2015 WL 1421836, *4 (Fed. Cir. 2015) ("The context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning of those *terms*.") (citation omitted). When examined in the context of the entire claims of the '401 and '835 Patents, the terms should not be construed in isolation to require an empty space.

The claims of the '401 and '835 Patents include the term "hollow interior" in relation to where components and/or agents are "disposed." *Phillips*, 415 F.3d at 1314 ("[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms."). Claim 1 of the '401 Patent requires that "the marker, biocompatible component and agent are disposed of within the hollow interior." Similarly, claim 9 requires that "the hollow interior comprises a biocompatible component, and wherein the marker component and the agent are dispersed in the biocompatible component." And claim 20 of the '835 Patent requires that "the agent is disposed within the hollow interior of the tube." Interpreting "hollow interior" in the entire context of these claims, as well as others where the term appears, shows that the term does not sit in isolation, but is in reference to space that could be filled with components and/or agents, *i.e.*, an "interior space." It is without regard to whether "empty spaces" existed after such components and/or agents were dispensed. *See IOEnginve, LLC v. Interactive Media Corp.*, No. 14-1571-GMS, 2016 WL 1121938, at *1 n.4 (D. Del. Mar. 21, 2016) (finding claim terms should be given plain and ordinary meaning where "meaning of the[] terms is clear when considered in the context of the entire claim"); *Depomed*, 2015 WL 1421836, *4 (adopting plaintiff's proposed construction where defendant's would render term "inappropriately ambiguous when considering the surrounding context" of the claim language); *see also Intel Corp. v. Future Link Sys., LLC*, No. 14-377-LPS,

2016 WL 4162648, at *4 (D. Del. Aug. 2, 2016) (rejecting defendant's proposed construction as contrary to "the surrounding claim language").

Furthermore, the specification supports that the terms should be given their plain and ordinary meaning as proposed by Microspherix. Referring to Figure 2, the specification discloses "a brachytherapy strand 10 is shaped into a hollow tube 18 having a cylindrical cavity 20" that in preferred versions "is sized to ***accept and envelop*** a standard-sized brachytherapy strand," and that the "[h]ollow tube 18 can have any wall thickness or length suitable for ***wholly or partially*** enveloping a standard-sized brachytherapy strand." ('402 Patent at 15:24–39 (emphasis added).) This specification language supports that the "hollow interior" is just an interior space where the agent and/or other components are disposed, without regard to an "empty space" post-disposal.

Merck's constructions, however, are unsupported by the intrinsic evidence. Merck broadly cites to all claims of the '401 and '835 Patents as support (D.I. 94, Ex. A at 3), and the portions of the specifications that Merck cites fail to provide support for requiring an empty space. (*See id.* (citing '401 Patent at 4:25–29, 14:43–47, 15:14–37, 16:15–20, 17:44–56, Figs. 1 and 2 (and all passages in the specification referring to those figures)).) Nothing in the specification or elsewhere in the intrinsic evidence suggests that the inventor intended to depart from the meaning of "hollow interior" when interpreted in the context of a space where agents and/or components are disposed within. *See Phillips*, 415 F.3d at 1312 ("We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.'") (citation omitted). Rather, as discussed above, the intrinsic evidence supports Microspherix's proposal of plain and ordinary meaning, *i.e.*, "interior space" and "wherein the agent is disposed within the interior space of the tube."

Merck's non-infringement driven proposals interpret "hollow interior" in isolation, improperly read in the limitation of an "empty space," and should be rejected. *See Vita-Mix Corp.*

v. Basic Holding, Inc., 581 F.3d 1317, 1324 (Fed. Cir. 2009) ("Claims are properly construed without the objective of capturing or excluding the accused device."); *see also Liebel-Flarsheim*, 358 F.3d at 906 ("[C]laims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction'") (citation omitted).

G. "flexible"

Claim Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"flexible"	Not indefinite, plain and ordinary meaning, "not rigid or flaccid"	Indefinite, alternatively: "capable of bending"

Microspherix submits that no construction beyond the plain and ordinary meaning is necessary because "flexible" is clear, simple, and well understood. *See U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) ("The *Markman* decisions do not hold that the trial judge must repeat or restate every claim term in order to comply with the ruling that claim construction is for the court."). Furthermore, "flexible" should be accorded its plain and ordinary meaning because it is "unambiguous to a POSITA." *See Eagle View Tech., Inc. v. Xactware Sols., Inc.*, No. 15-07025 (RBK/JS), 2017 WL 6025364, at *4 (D.N.J. Dec. 5, 2017).

The plain and ordinary meaning proffered by Microspherix is consistent with the specification. *See Merck & Co.*, 347 F.3d at 1371. When describing the flexibility of an object, the specification consistently characterizes a flexible object as being not "rigid" or "flaccid." ('402 Patent at 22:32–35 ("Where the chain is endowed with the flexibility of an elastic polymer or similar substance, the chain may be considered to be ***variably flexible rather than rigid or flaccid***.") (emphasis added); *id.* at Abstract ("Strands can be formed as chains or continuous arrays of seeds up to 50 centimeters or more, with or without spacer material, ***flaccid***, ***rigid***, or flexible.")

(emphasis added); *id.* at 4:8–11 (same); *id.* at 22:23–25 ("Where the spacer is made of a relatively flexible material, the chain can be relatively ***flaccid***.") (emphasis added).)

Indeed, many courts that have considered this term afforded "flexible" its plain and ordinary meaning. *See, e.g.*, *QXMédical, LLC v. Vascular Sols., LLC*, No. 17-CV-1969 (PJS/TNL), 2018 WL 5617568, at *6 (D. Minn. Oct. 30, 2018) ("flexible" given plain and ordinary meaning in case concerning coaxial guide catheter); *Solannex, Inc. v. Miasole, Inc.*, C 11-00171 PSG, Dkt. 182 at 1 (N.D. Cal. Apr. 10, 2013) ("[f]lexible" given plain and ordinary meaning); *Ultradent Prods., Inc. v. Hayman*, No. CV-00-13402 MRP (CTx), 2002 WL 34477127, at *14 (C.D. Cal. Jan. 11, 2002) ("[T]he ordinary and plain meaning of 'flexible' is manifest. Therefore, the word 'flexible' requires no construction.").

Merck's construction unnecessarily limits "flexible" to "capable of bending," which is inconsistent with the specification. *See Merck & Co.*, 347 F.3d at 1371. For example, a strand that can be extended in its longitudinal direction would not be considered "flexible" under Merck's construction at least because longitudinal extension is not bending. However, the specification of the Asserted Patents clarifies that "[t]his flexibility, rather than being simply linear or curved, can be in ***any*** direction." (*E.g.*, '402 Patent at 22:40–41 (emphasis added).) Merck's construction that goes against the teaching of the specification cannot be correct. *See Phillips*, 415 F.3d at 1315; *Depomed*, 2012 WL 3201962, at *14–15.

As for definiteness, contrary to Merck's contention, "flexible" is not indefinite because the specification provides illustrations to "inform those skilled in the art about the scope of the invention with reasonable certainty."[10] *Nautilus, Inc. v. Biosig Inst., Inc.*, 134 S. Ct. 2120, 2129

[10] To the extent that the Court believes that definiteness issues should not be decided during claim construction, the Court should decide this issue after both parties' experts have a chance to weigh in on this issue.

(2014). But "[t]erms of degree are not 'inherently indefinite,' and 'absolute or mathematical precision is not required.'" *One-E-Way, Inc. v. Int'l Trade Com'n*, 859 F.3d 1059, 1068 (Fed. Cir. 2017) (citation omitted). "All that is required is some standard for measuring the term of degree." *Exmark Mfg. Co. v. Briggs & Stratton Power Prods. Grp.*, 879 F.3d 1332, 1346 (Fed. Cir. 2018). Indeed, Merck's expert witness for the IPR Proceedings unequivocally admitted that a POSA "would know" how to make a flexible implant. (*See* Ex. 7 ('402 IPR, Langer Dep. Tr.) at 135:19–23 (Q. So a person of skill in the art would know if the goal is to create a flexible implant how to do that, fair? A. Yes. You'd probably -- yes, I would say that's right.).)

To be sure, the Asserted Patents provide "some standard for measuring the term of degree." *Exmark Mfg. Co.*, 879 F.3d at 1346. A standard for measuring the term of degree can be found if "[t]he specification provides [] examples of [the limitation], including some criteria for selecting them." *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1334 (Fed. Cir. 2010); *see also Sonix Tech. Co. v. Publ'ns Int'l, Ltd.*, 844 F.3d 1370, 1377 (Fed. Cir. 2017); *Promethean Insulation Tech. LLC v. Reflectix, Inc.*, 2:15-cv-00028-JRG-RSP, 2015 WL 9093824, at *5–6 (E.D. Tex. Dec. 16, 2015).

Promethean is informative here. In *Promethean*, the court held that "flexible" and "flexibility" were not indefinite. 2015 WL 9093824, at *6. In reaching its conclusion, the court noted that "flexible" is "used in the claims as [a] term[] of degree" and "[t]he [patent-in-suit] provide[d] a standard for determining whether a particular degree of flexibility satisfies the flexible and flexibility limitations." *Id*. at *5–6 ("As Plaintiff stated in its opening brief, the terms require the claimed product to be 'flexible enough' for wrapping applications."). In particular, the court held that the patent provided a standard for determining flexibility because it provided

contemplated applications and examples of the applications. *See id.* at *6. Specifically, the court noted:

> The claim language itself states that the claimed product must be flexible for "wrapping applications." . . . And the patent provides examples of the kind potential wrapping applications contemplated: . . . . The patent discloses insulation suitable to wrap objects of a size comparable to water heaters, water pipes, and air ducts. As such, the patent provides a standard for sufficient flexibility.

Id.

Here, "flexible" is also used in the claims as a term of degree. (*See* '402 Patent at 22:32–37 ("Where the chain is endowed with the flexibility of an elastic polymer or similar substance, the chain may be considered to be ***variably flexible*** rather than rigid or flaccid. The precise ***degree of flexibility*** will depend upon the composition of the carrier matrix.") (emphasis added); *id.* at 19:59–62 ("The hairs were made as long as possible, and have ***sufficient flexibility*** so that individual tips can attach to uneven surfaces all at the same time, and do not break, curl or tangle.") (emphasis added); *id.* at 22:23–25 ("Where the spacer is made of a ***relatively flexible*** material, the chain can be relatively flaccid.") (emphasis added).) Also, "[the Asserted Patents] provide[] a standard for determining whether a particular degree of flexibility satisfies the flexible and flexibility limitations" by providing contemplated applications and examples of the applications. *Promethean*, 2015 WL 9093824, at *6. The claim language provides that the contemplated applications of the claimed invention are "implantation into a subject." (*See, e.g.*, '401 Patent, Claim 1.) Further, the specification of the Asserted Patents provides examples of the contemplated implantation—in a patient's bodily tissue, such as breasts, viscera, and prostate. ('402 Patent at 19:14–21; *id.* at 20:58–63; *id.* at 22:29–32.) Indeed, "[t]hose skilled in the art will be accustomed to selecting the ratio[] of component substances in the carrier matrix such that the desired degree of flexibility is achieved." ('402 Patent at 22:37–40.) Thus, because the Asserted Patents also

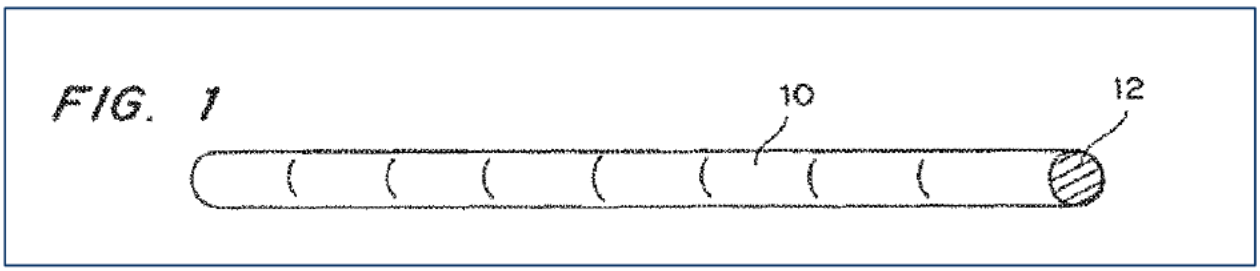
provide contemplated applications and examples of the relevant applications, like *Promethean*, this Court should also find the term "flexible" definite.

H. "rod"

Claim Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"rod"	Plain and ordinary meaning, "cylinder-shaped device"	"a unitary cylinder"

"Rod" is also a term that requires no construction because the proper scope and meaning are clear and understandable to the jury without explanation. *See U.S. Surgical Corp.*, 103 F.3d at 1568. In other words, no construction is needed because the term "rod" "would have been readily understandable to a layperson as well as a person of ordinary skill in the art." *Mars, Inc. v. JCM Am. Corp.*, No. 05-3165(RBK), 2008 WL 2684118, at *8 (D.N.J. July 2, 2008). Indeed, a court in this Circuit once held that "rod" required no construction. *See Applera Corp. v. Micromass UK Ltd.*, 186 F. Supp. 2d 487, 508 (D. Del. 2002) ("[Plaintiff] believes such a construction by the court to be unnecessary because 'a rod is a rod.' The court agrees and believes the proper construction of rod to be self-evident.").

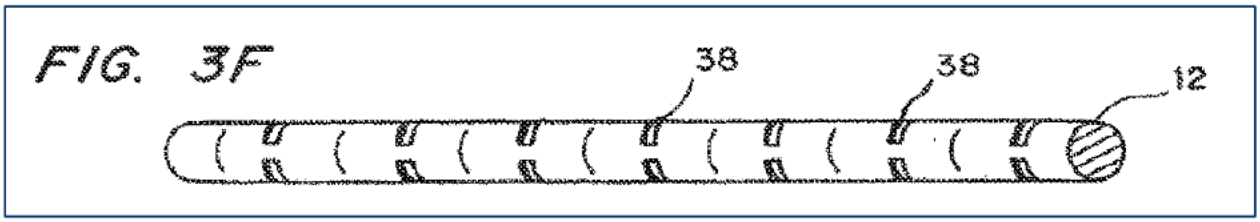
To the extent that a construction is necessary, the plain and ordinary meaning proffered by Microspherix is consistent with the specification of the Asserted Patents. (*See, e.g.*, '402 Patent at Fig. 1 (showing a cylindrically shaped strand); 14:66–15:5 (describing strand as "cylindrically shaped"); 14:62–66 (seeds can be shaped into a cylinder or a rod); 22:54–59 (seeds are "rod or cylinder-shaped").) Figure 1 of the '402 Patent, showing a cylindrically shaped strand, which can be "in the form of a rod," is reproduced below. ('402 Patent, Fig. 1, Claim 6.)



Although Merck does not dispute that a rod is cylindrical, its proposed construction attempts to limit a "rod" to a "unitary" cylinder. Such a construction is inconsistent with the specification and needlessly complicates a simple and straightforward term. *See Merck & Co.*, 347 F.3d at 1371; *Depomed*, 2012 WL 3201962, at *14–15; *WCM Indus., Inc. v. IPS Corp.*, No. 2:13-cv-02019-JPM-tmp, 2014 WL 8508559, at *31 (W.D. Tex. Nov. 10, 2014) ("These two terms are not found in the relevant claim language in any of the Asserted Patents. Including [them] in the construction unnecessarily complicates the meaning of the term.").

Merck's construction is inconsistent with the specification because it reads out some embodiments in the specification. *See Phillips*, 415 F.3d at 1316 (instructing that "claims must be construed so as to be consistent with the specification"); *Ateliers de la Haute-Garonne v. Broetje Automation-USA Inc.*, No. 09-598-LPS, 2011 WL 722937, at *9, *11 (D. Del. Feb. 23, 2011) (finding construction inconsistent with specification when it is inconsistent with at least one embodiment). The claimed rod can comprise more than one single cylinder. In one embodiment, the specification provides that "[s]trands can be formed as chains or continuous arrays of seeds." ('402 Patent at 4:8–11.) As explained by the claims and the specification of the '402 Patent, the strand can be "in the form of a rod," and seeds can be "shaped into a cylinder." (*Id.*) Thus, rods can be formed as chains or continuous arrays of cylinders, which is inconsistent with Merck's proposed unitary construction. In another embodiment, the specification of the Asserted Patents describes a strand that can be in the form of a rod, comprising a number of smaller strands. (*See*

id. at Fig. 3F (reproduced below), 17:61–18:3.) Merck's construction would exclude those embodiments. *See Invitrogen Corp.*, 327 F.3d at 1369; *Verizon Servs. Corp.*, 503 F.3d at 1305; *Depomed*, 2012 WL 3201962, at *14–15. Thus, the Court should reject Merck's proposed construction and give "rod" its plain and ordinary meaning.



VI. CONCLUSION

For the reasons discussed above, Microspherix respectfully requests that the Court adopt its proposed constructions of the disputed terms.

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